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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,373	02/18/2004	Jesse L. Beauchamp	1950-0024	3556
23980	7590	09/13/2007		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C 1400 PAGE MILL ROAD PALO ALTO, CA 94304-1124			EXAMINER COVINGTON, RAYMOND K	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/782,373

Applicant(s)

BEAUCHAMP ET AL.

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-25, and 27-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using benzoic acid, ethylenediamine, propylenediamine, butanediamine, hexamethylenediamine, N,N'-dimethylethylenediamine, diethylenetriamine, dipropylenetriamine, triethylenetriamine, tetramethylethylenediamine, N,N'-dimethylpropylenediamine, N,N,N',N''-tetramethylethylenediamine, N,N,N',N''-tetramethyl-1,3-propanediamine, hexamethylenetetramine, diazabicyclononane, sparteine, phenantroline, 2,2'-bipyridine and neocuproine transition metal binding groups, diazo groups and compounds 1-5, does not reasonably provide enablement for heteroalkyls, heteroalkenyls, heteroaryls, and alkylheteroaryls, all amine group containing compounds, all cyclic ethers, all acidic groups, all transition binding groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. There is insufficient disclosure of starting materials that

would place such a diverse genus of compounds in possession of the public in the event of a patent grant.

Scope of 3- to 24-membered heterocyclics having 1 to 4+ heteroatoms to include all known heterocyclics, heteroaryls, heteroaromatics is not adequately enabled. A review of the specification shows none described as representative of actual working examples.

The limited data provides no clear evaluation of how the remaining scope with up to, e.g., 4+ hetero atoms in any array. Likewise examples for heteroalkyls and heteroalkenyls etc.

There is thus no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other ring systems might work this rejection is applied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-6,8,10-13 are, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The numerous substituent variables and their voluminous complex meanings and their seemingly endless permutations and combinations make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter. As presented, the subject matter cannot be regarded as being a clear and concise description for which protection is sought and as such the listed claims are indefinite.

Though clearly one of ordinary skill in the art could identify much of what is within the scope of the A, the delineation between what is and what is not claimed has not been circumscribed. That is, all of what is claimed is not identifiable. In claim 1, "heteraryl group" is one of the definitions. The specification provides no examples of what these terms may signify, and does not limit them to any particular definition. For example, page 5-6 teach many examples of groups, but this section is prefaced with "may include," so it is clear that applicants do not wish to be limited. Again, where the delineation between claimed subject matter

and unclaimed subject matter lies is unclear from a reading of the claims in light of the specification. More than one definition of the general term "heterocyclic" or "heterocycle" is accepted by those of ordinary skill in the art of organic chemistry. Some consider cyclic organic compounds wherein at least one carbon atom is replaced by sulfur, oxygen or nitrogen to be heterocyclic compounds, while others of ordinary skill include selenium, tellurium, boron or tin containing rings to be within the scope of the term "heterocyclic" as it is commonly used, and some definitions of "heterocyclic" do not require carbon to be present at all.

The examiner directs applicants' attention to the following three references: On page 282 of the McGraw-Hill Dictionary of Chemical Terms (1990), the definition of "heterocyclic compound" is a compound in which the ring structure is a combination of more than one kind of atom. On page 490 of the Concise Encyclopedia Chemistry (1993), the definition of "heterocycles" is cyclic hydrocarbon compounds in which the ring consists of carbon and at least one other element, usually, N, O or S. The definition goes on to explain that the possibilities for synthesis are nearly unlimited, and that compounds wherein the heteroatoms are of elements like phosphorous, arsenic, selenium, and tellurium are being incorporated with increasing frequency. On page 594 of Hawley's Condensed Chemical Dictionary (1993), "heterocyclic" is defined as a closed-ring structure,

usually, either 5 or 6 members, in which one or more of the atoms in the ring is an element other than carbon, e.g, sulfur, nitrogen, etc. These three definitions should make it abundantly clear that there is no one specific and exact definition of the word "heterocyclic," thus when this term is present as a claim limitation, the metes and bounds of protection are not pointed out and distinctly claimed. Though the three above-cited definitions of the term have some shared aspects, chemists of ordinary skill would not necessarily agree on the full scope and meaning of the term "heterocyclic." The limited disclosure and exemplification, noted in the previous office action, does not enable this vast scope. There is no predictability between, for example NH₂ and methylamine-crown ether. To determine which of, for example, all known acidic groups would work in the claimed process would require undue experimentation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-25, 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way to convey

reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The issue concerning the meaning of phrases "amine group containing compounds, cyclic ether, acidic groups, transition binding groups and diazo groups are discussed above." Claims 1-3, 5-25, 27-33 do not contain a complete generic formula.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such

identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.”

The Court of Appeals for the Federal Circuit held in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 at 1406. “[a] written description of an invention involving a chemical genus, like a description of a chemical species, “requires a precise definition, such as by structure, formula, [or] chemical name, “of the claimed subject matter sufficient to distinguish it from other materials. *In re Smythe*, 480 F.2d 1376, 1383, *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .”).” Applicants’ functional definitions in the claimed formula simply lack the precision required by the Court of Appeals for the Federal Circuit.

As discussed above the phrase “amine containing compounds, crown ether, acidic groups, transition binding groups and diazo groups are discussed above.” is

not art recognized in organic chemistry. According to the MPEP §2163.02

Standard for Determining Compliance With the Written Description Requirement,

“The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed”. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter”. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).”

Thus, one of ordinary skill in the art, who would use Applicants' compounds, would not know what “Amine containing compounds, crown ether, acidic groups, transition binding groups and diazo groups”. That one of ordinary skill would not have understood the inventor to be in possession of the claimed invention”at the time of filing.

The terms do not bring to mind a particular structure. It is important whether the term is one that is understood to describe structure, as opposed to a term that is simply a nonce phrase or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term "means for." In *Mas-*

Hamilton Group v. LaGard, Inc., 48 USPQ2d 1010 *Lighting World Inc. v. Birchwood Lighting Inc.*, 72 USPQ2d 1344 at 1351.

According to MPEP §2106.02, "it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that **factual affidavits** could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979)."

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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